

RECEIVED
CENTRAL FAX CENTER

DEC 16 2008

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : December 16, 2008
LISZIEWICZ, et al. : Atty Docket No. RGT 9771
Serial No. 10/081,922 : Group 1632
Filed: 15 September 1998 : Examiner: Wilson

For: Method of Delivering Genes into Antigen
Presenting Cells of the Skin

Commissioner of Patents
P.O. Box 1450
Alexandria, VA 22313-1450

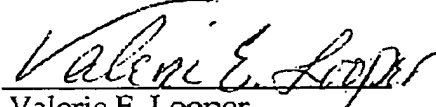
Fax: (571) 273-8300

BRIEF ON APPEAL¹

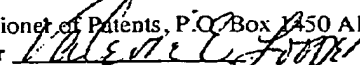
Following a Notice of Appeal filed October 16, 2008 together with a petition for a three-month extension of time, kindly enter the enclosed Brief of record. A credit card form for the fee set forth in § 41.20(b)2 is enclosed. The Commissioner is authorised to charge any additional fees due, or credit any overage, to Deposit Account No. 50-0855.

The applicant remains entitled to the previously-claimed small entity status.

Respectfully Submitted,


Valerie E. Looper
Registration No. 33,007

The Law Offices of
Valerie E. Looper
11726 Lightfall Court
Columbia, Maryland 21044
Telephone: (410) 715 - 5771
fax: (410) 715-5771
email: alexanderlooper@comcast.net

¹ This paper is being forwarded by fax to the Commissioner of Patents, P.O. Box 1450 Alexandria, VA 22313-1450 on December 16, 2008. Signed Valerie E. Looper 

RGT 9771 PCT

USSN 10/081,922
December 16, 2008

REAL PARTY IN INTEREST

The real party in interest in this case is Genetic Immunity, Inc., a Delaware corporation having an office at 8300 Greensboro Drive, McLean Virginia 22102.

RELATED CASES

As of December 16, 2008, there are no appeals and interferences related to this case. A Notice of Appeal was previously filed in this case Nov. 6, 2006, and an Appeal Brief was filed 5 January, 2007. Prosecution was re-opened by action of the Examiner July 12, 2007. This case is a Division of USPN 6,420,176, which relates to a novel composition of matter. A provisional double-patenting rejection has been made of the inventors' USSN 08/803,484, which relates to a new use for a known class of DNA.

JURISDICTION

This is an appeal under 35 USC 134(a) from a Final Rejection bearing a mail date of April 16, 2008 and setting a shortened 3-month statutory period for reply. A Notice of Appeal together with a petition for a 3-month extension of time and the applicable fee was filed October 16, 2008. Under B. R. 41.37, the due date for this brief is December 16, 2008.

RGT 9771 PCT

USSN 10/081,922
December 16, 2008**TABLE OF CONTENTS**

REAL PARTY IN INTEREST	2
RELATED CASES	2
JURISDICTION.....	2
TABLE OF CONTENTS.....	3
TABLE OF AUTHORITIES.....	5
STATUS OF AMENDMENTS	6
GROUND OF REJECTION.....	6
STATEMENT OF FACTS	8
INTRODUCTION	8
I. OBJECTION TO CLAIMS 23-26, 28, 30-33, 35 AND 40-44 UNDER 35 USC § 112, 1ST PARA., NEW MATTER, "DNA AND A SUGAR, OR POLYETHYLENEIMINE, OR POLYETHYLENIMINE DERIVATIVES."	8
II. OBJECTION TO CLAIM 30 UNDER 35 USC § 112, 2ND PARA., MOLAR RATIO.....	9
III. REJECTION OF CLAIMS 23-26, 28, 30-32, 35 AND 40, 41 AND 43-44 UNDER 35 USC 102(E) AS BEING ANTICIPATED UNDER BEHR (USPN 6,013,240, JAN 11, 2000; 102(E) DATE=2-28-97) AS SUPPORTED BY LIU (VACCINE, 2002, VOL. 20, PG 42-48), MITTAL (J. GENERAL VIROL., JAN. 1996, VOL. 77, PG 1-9, ABSTRACT ONLY) AND KUBY (ED., IMMUNOLOGY, 1992, W.H. FREEMAN AND COMPANY, CHAPTER 1, "ACQUIRED IMMUNITY," PG 8-9).	10
IV. REJECTION OF CLAIMS 23-26, 28, 30-32, 35, 40, 41, 43 AND 44 UNDER 35 USC 103(A) FOR OBVIOUSNESS OVER BEHR (US PATENT 6,013,240, JAN. 11, 2000) AS SUPPORTED BY LIU (VACCINE, 2002, VOL. 20, PG 42-48), MITTAL (J. GENERAL VIROL., JAN. 1996, VOL. 77, PG 1-9, ABSTRACT ONLY) AND KUBY (ED., IMMUNOLOGY, 1992, W.H. FREEMAN AND COMPANY, CHAPTER 1, "ACQUIRED IMMUNITY," PG 8-9) AND IN VIEW OF HOLLER (US PATENT 5,908,923).....	14
V. CLAIMS 23-26, 28, 30-33, 35 AND 40-43 REMAIN AND CLAIM 44 IS PROVISIONALLY REJECTED ON THE GROUND OF NONSTATUTORY OBVIOUSNESS-TYPE DOUBLE PATENTING AS BEING UNPATENTABLE OVER CLAIMS 58-71 OF COPENDING APPLICATION NO. 08/803484 IN VIEW OF THE DISCLOSURE OF '484.....	27
VI. OBJECTION TO CLAIMS 23-26, 28, 30-33, 35 AND 40-44 UNDER 35 USC § 112, 1ST PARA., NEW MATTER, "WITHOUT THE USE OF A NEEDLE."	28
ARGUMENT	28
I. OBJECTION TO CLAIMS 23-26, 28, 30-33, 35 AND 40-44 UNDER 35 USC § 112, 1ST PARA., NEW MATTER, "DNA AND A SUGAR, OR POLYETHYLENEIMINE, OR POLYETHYLENIMINE DERIVATIVES."	28
II. OBJECTION TO CLAIM 30 UNDER 35 USC § 112, 2ND PARA., MOLAR RATIO.....	29
III. REJECTION OF CLAIMS 23-26, 28, 30-32, 35 AND 40, 41 AND 43-44 UNDER 35 USC 102(E) AS BEING ANTICIPATED UNDER BEHR (USPN 6,013,240, JAN 11, 2000; 102(E) DATE=2-28-97) AS SUPPORTED BY LIU (VACCINE, 2002, VOL. 20, PG 42-48), MITTAL (J. GENERAL VIROL., JAN. 1996, VOL. 77, PG 1-9, ABSTRACT ONLY) AND KUBY (ED., IMMUNOLOGY, 1992, W.H. FREEMAN AND COMPANY, CHAPTER 1, "ACQUIRED IMMUNITY," PG 8-9).	30

RGT 9771 PCT

USSN 10/081,922
December 16, 2008

IV. REJECTION OF CLAIMS 23-26, 28, 30-32, 35, 40, 41, 43 AND 44 UNDER 35 USC 103(A) FOR OBVIOUSNESS OVER BEHR (US PATENT 6,013,240, JAN. 11, 2000) AS SUPPORTED BY LIU (VACCINE, 2002, VOL. 20, PG 42-48), MITTAL (J. GENERAL VIROL., JAN. 1996, VOL. 77, PG 1-9, ABSTRACT ONLY) AND KUBY (ED., IMMUNOLOGY, 1992, W.H. FREEMAN AND COMPANY, CHAPTER 1, "ACQUIRED IMMUNITY," PG 8-9) AND IN VIEW OF HOLLER (US PATENT 5,908,923)..... 31

V. CLAIMS 23-26, 28, 30-33, 35 AND 40-43 REMAIN AND CLAIM 44 IS PROVISIONALLY REJECTED ON THE GROUND OF NONSTATUTORY OBVIOUSNESS-TYPE DOUBLE PATENTING AS BEING UNPATENTABLE OVER CLAIMS 58-71 OF COPENING APPLICATION NO. 08/803484 IN VIEW OF THE DISCLOSURE OF '484..... 35

VI. OBJECTION TO CLAIMS 23-26, 28, 30-33, 35 AND 40-44 UNDER 35 USC § 112, 1ST PARA, NEW MATTER, "WITHOUT THE USE OF A NEEDLE." 36

APPENDIX 37

APPENDIX - CLAIMS CONFIRM LIST OF OBJECTIONS/REJECTIONS 37
APPENDIX - CLAIM SUPPORT 39
APPENDIX - DRAWING ANALYSIS 42
APPENDIX - EVIDENCE 43
APPENDIX - RELATED CASES 46

RGT 9771 PCT

USSN 10/081,922
December 16, 2008**TABLE OF AUTHORITIES****Cases**

Animal Legal Defense Fund v. Quigg, 18 USPQ 2d 1677, 1685, Fed. Cir. (1985)	24
Ex parte Erlich, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986)	26
In re Antonie, 559 F.2d 618, 620, 195 USPQ 6,8 (CCPA 1977)	25
In re Brink, 419 F.2d 914, 918, 164 USPQ 247 (1970)	13
In re Gordon, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)	26
In re Kahn, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006)	25
In re Linter, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972)	25
In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990)	26
In re Rasmussen, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981)	29
In re Ratti, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)	27
In re Rijckaert, 9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993)	25
In re Roberts, 169 F.3d 743, 49 USPQ2d 1949 (1999)	13
In re Young, 927 F.2d 588, 18 USPQ2d 1089 (Fed. Cir. 1991)	26
KSR International Co. v. Teleflex Inc., 550 U.S. ___, ___, 82 USPQ2d 1385, 1395 (2007)	26

Statutes

35 USC § 102	12
35 USC § 103	24

MPEP

MPEP 2112.02	12
MPEP 2131	12
MPEP 2131.01	12
MPEP 2131.01 I	12
MPEP 2131.01 II	12
MPEP 2141.02 V	25
MPEP 2142.01	24
MPEP 2143.01	25
MPEP 2143.01 II	26
MPEP 2143.01 V	26
MPEP 2143.01 VI	27
MPEP 2143.02 III	26
MPEP 2163.01	29
MPEP 2163.06	29

RGT 9771 PCT

USSN 10/081,922
December 16, 2008**Articles**

Arthur, J. F et al. Cancer Gene Therapy. 4:1 17-21, 1997	18
Arthur, J. F. et al., Cancer Gene Therapy 4:1 17-21, 1997	22
Pollard H; Remy JS; Loussouarn G; Demolombe S; Behr JP; J Biol Chem 1998 Mar 27;273 (13):7507-11	18

STATUS OF AMENDMENTS

No amendment has been filed after the final rejection. The last paper on behalf of the Applicants was filed December 12, 2007.

GROUND OF REJECTION

- I. Objection to Claims 23-26, 28, 30-33, 35 and 40-44 under 35 USC § 112, 1st para., New matter, "DNA and a sugar, or polyethyleneimine, or polyethylenimine derivatives."
- II. Objection to Claim 30 under 35 USC § 112, 2nd para., molar ratio
- III. Rejection of Claims 23-26, 28, 30-32, 35 and 40, 41 and 43-44 under 35 USC 102(e) as being anticipated under Behr (USPN 6,013,240, Jan 11, 2000; 102(e) date=2-28-97) as supported by Liu (Vaccine, 2002, Vol. 20, pg

RGT 9771 PCT

USSN 10/081,922
December 16, 2008

42-48), Mittal (J. General Virol., Jan. 1996, Vol. 77, pg 1-9, abstract only) and Kuby (ed., Immunology, 1992, W.H. Freeman and Company, Chapter 1, "Acquired Immunity," pg 8-9).

IV. Rejection of Claims 23-26, 28, 30-32, 35, 40, 41, 43 and 44 under 35 USC 103(a) for obviousness over Behr (US Patent 6,013,240, Jan. 11, 2000) as supported by Liu (Vaccine, 2002, Vol. 20, pg 42-48), Mittal (J. General Virol., Jan. 1996, Vol. 77, pg 1-9, abstract only) and Kuby (ed., Immunology, 1992, W.H. Freeman and Company, Chapter 1, "Acquired Immunity," pg 8-9) and in view of Holler (US Patent 5,908,923).

V. Claims 23-26, 28, 30-33, 35 and 40-43 remain and claim 44 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 58-71 of copending Application No. 08/803484 in view of the disclosure of '484.

VI. Objection to Claims 23-26, 28, 30-33, 35 and 40-44 under 35 USC § 112, 1st para, New matter, "without the use of a needle."

RGT 9771 PCT

USSN 10/081,922
December 16, 2008

STATEMENT OF FACTS

Introduction

The presently claimed invention relates to a new method of administering a vaccine that does not require use of a needle. (App, p. 25, lines 12-13) It has the advantages of being simple, inexpensive (line 15), applicable to a broad range of diseases (lines 17-21), and painless (lines 24-25). In a key experiment (Example 8), DNA complexed with various materials was applied to the prepared skin on the backs of mice for one hour or subcutaneously, and the results were shown in Table 2 (page 23). In Experiment No. 5 of Example 8, DNA formulated in glucose solution and administered transcutaneously performed sixteen times better than the same formulation administered by subcutaneous injection.

I. Objection to Claims 23-26, 28, 30-33, 35 and 40-44 under 35 USC § 112, 1st para., New matter, "DNA and a sugar, or polyethyleneimine, or polyethylenimine derivatives."

The Examiner has objected that the language in Claim 23 "DNA and a sugar, or polyethyleneimine, or polyethylenimine derivatives," is new matter. In a Preliminary Amendment for this divisional application filed February 21, 2002, the Applicants pointed out that Claims 23-41 corresponded to the original Class II of the parent application USSN 09/153,1578. And indeed, in an

RGT 9771 PCT

USSN 10/081,922
December 16, 2008

Amendment filed June 7, 2004 at page 6, the applicants pointed out specifically that the Examiner quoted original Claim 8 as including the following language: "wherein the complex is selected from the group consisting of DNA conjugates of sugars, polyethylenimine, polyethylenimine derivatives, and mixtures thereof." Further, the Applicants pointed out Examples 6, 7 and 10 in the parent patent, that include a variety of combinations, including DNA, DNA with PEI, DNA and PEI derivatives (-mannose, -galactose and -glucose), some in saline and some in glucose solution. Applicants now point out that DNA and a sugar, DNA and PEI, and DNA and a PEI-derivative (PEI-man) are all found in Table 2, because all were formulated in a sugar solution (page 22, line 35).

II. Objection to Claim 30 under 35 USC § 112, 2nd para., molar ratio

Claim 30 "The method of Claim 26, wherein the complex comprises a 5:1 ratio of mannosylated polyethylenimine nitrogen per DNA phosphate," has been objected to for lack of clarity. Support for this Claim is found at page 22 of the application, lines 9-16, where, to form a neutral complex, the ratio of PEI-man to DNA is 5:1 (lines 11-12). A different ratio applies if the complex is PEI-DNA. Then the ratio of PEI to DNA is 3:1 (line 12).

At item II, page 5 of an office action dated April 16, 2008, the Examiner has objected that mannosylated polyethylenimine nitrogen is not distinguished

RGT 9771 PCT

USSN 10/081,922
December 16, 2008

from polyethylenimine nitrogen and that Claim 30 does not clearly limit the complex to having mannosylated polyethylenimine, and does not further limit Claim 26.

III. Rejection of Claims 23-26, 28, 30-32, 35 and 40, 41 and 43-44 under 35 USC 102(e) as being anticipated under Behr (USPN 6,013,240, Jan 11, 2000; 102(e) date=2-28-97) as supported by Liu (Vaccine, 2002, Vol. 20, pg 42-48), Mittal (J. General Virol., Jan. 1996, Vol. 77, pg 1-9, abstract only) and Kuby (ed., Immunology, 1992, W.H. Freeman and Company, Chapter 1, "Acquired Immunity," pg 8-9).

A. Contents of the File Wrapper

This is a new rejection. The original anticipation rejection over Behr in an office action dated March 10, 2004, starting at page 16. In an amendment filed June 24, 2004, the applicants amended the Claims to recite all the limitations of the single claim not subject to the rejection, and the rejection was not withdrawn. Instead, the Carson reference was added to the rejection in an office action dated Sept. 22, 2004, starting at page 23, and stated that the phrase "A method of transfecting antigen presenting cells" was not being given patentable weight because *it may not occur* (emphasis added) at page 24, lines 2-3.

The rejection for anticipation by Behr as supported by Carson, Mittal and Kuby has been withdrawn after the applicants pointed out in a paper filed